REMARKS

Claims 88-105 are currently pending in the subject application. Applicant has hereinabove added new claim 106. Support for new claim 106 can be found in the specification as originally filed at page 2, lines 27-35.

Rejection Under 35 U.S.C. §112, Written Description

In the September 3, 2008 Final Office Action issued in connection with the above-identified application the Examiner rejected claims 89-105 as allegedly containing subject matter not described in the specification so as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The Examiner states that the application has a single example of a tablet which contains, inter alia, 2.5mg oxandrolone. The Examiner further stated that the "application merely mentions 10-milligram dosage, but does not disclose further information as to the carrier and particular forms." In addition, in the December 30, 2008 Advisory Action the Examiner maintained the rejection and directed the applicant's attention to *Fujikawa v. Wattanasin*, 39 USPQ2d 1895, 1905 (Fed. Cir. 1996) and *In re Ruschig*, 154 USPQ 118, 123 (CCPA 1967). The Examiner also stated in the Advisory Action that "[n]owhere in the application teach that the 10mg dose has to be in a unit dosage, or in a tablet."

In response, applicant respectfully traverses the Examiner's rejection. Applicants enclose copies of each of *Fujikawa v. Wattanasin* and *In re Ruschig* as **Exhibits A and B**, respectively. Applicants note that in both the cited cases the claim found not to be supported was directed to a specific chemical species of a

disclosed chemical genus, wherein the genus disclosed substituents in generic form (e.g. alkyl) but the claim was directed to species (e.g. ethyl). Moreover, the specific species were not recited in the specification, and the courts indicated that there were no "guides" or "blaze marks" to direct one skilled in the art to the claimed species. Applicant directs the Examiner's attention to pages 1904 & 1905 of *Fujikawa v. Wattanasin* and pages 121 & 122 of *In re Ruschig*. Morever, *Fujikawa v. Wattanasin* did not have *ipsis verbis* support for the claimed compound and pointed to preferred embodiments of the claimed genus that did not align with the claimed species.

In contrast, applicant's presently claimed "10mg" dose has *ipsis verbis* support. In addition, there is no disclosure of a "preferred" embodiment which is other than what is claimed. Moreover, only a limited number of doses are disclosed. Finally, unlike the hundreds or thousands of different chemical compounds covered by the genus recited in each of the two cases cited by the Examiner, the subject application recites "as low as about" 2.5 mg, "as high as about" 20mg and actually recites, on page 4, line 4, a <u>10mg</u> dose.

Thus, the Examiner is trying to analogize between (a) situations in the cited cases where one skilled in the art is expected to understand that inventors are in possession of a particular species not explicitly disclosed from a disclosed genus comprising a large number or over 500,000 members (see page 1905 of *Fujikawa v. Wattanasin* and page 118 of *In re Ruschig*, respectively) and where the specific claimed compound has no *ipsis verbis* support to (b) the present situation where the genus is small, and the members are described. Moreover, as noted by the court in *Fujikawa v. Wattanasin* at page 1904, to satisfy the written description requirement "<u>the disclosure need only</u>

reasonably convey to persons skilled in the art that the inventor had possession of the subject matter in question" (emphasis added). Applicant submits it is not tenable that the disclosure does not reasonably convey possession of the claimed subject matter.

With regard to the Examiner's statement in the Advisory Action that "[n]owhere [does] the application teach that the 10mg dose has to be in a unit dosage, or in a tablet" (emphasis added), applicants note that on page 4, line 4, a 10mg dose is described and that the application also describes that the oxandrolone can be combined with "solid or liquid pharmaceutical carriers and formulated in unit dosage form..." (page 5, lines 19-22).

The Examiner's apparent requirement that it must be stated in the specification that the 10 mg dose "has to be in a unit dosage, or in a tablet support" (emphasis added) is not a requirement for the claim to meet the written description requirement. The question is whether the specification reasonably conveys to one skilled in the art that applicants were in possession of a 10mg unit dose form. As referenced above, the specification clearly discloses that doses can be between 2.5 and 20mg, it also discloses that one particular dose is the 10mg dose, and it also discloses that "[f]or purposes of administration in accordance with this invention, the active ingredient oxandrolone is combined with solid or liquid pharmaceutical carriers and formulated in unit dosage form..." (page 5, lines 19-22). Moreover, at page 7, line 35 to page 8, line 4 describes that "[e]xamples of suitable unit dosage forms in accordance with this invention are tablets, pills..". Thus, the disclosure clearly reasonably conveys to persons skilled in the art that the inventor had possession of the subject matter in question.

Accordingly, applicant respectfully submits the invention recited in the pending claims is fully described in the subject application and respectfully requests reconsideration and withdrawal of this ground of rejection.

Rejection Under 35 U.S.C. §103(a)

The Examiner rejected claims 88-105 under 35 U.S.C. §103(a) as allegedly obvious over Metcalf et al. (of record) in view of ANAVAR® (of record) and Babu et al. (U.S. Patent No. 5,073,380) and "further in view of applicant's admission at page 7." The Examiner alleged, inter alia, that it would have been prima facie obvious to one of ordinary skill in the art to make a dosage composition comprising 10mg oxandrolone. The Examiner asserted that a 10mg dosage form would have been obvious in view of the "the fact that it [would] have been used in the amount of 10mg, 20mg, and up to 150mg." The Examiner stated that one skilled in the art would be motivated to "make a tablet with 10mg of oxandrolone for those uses [of] more than 10mg a day." The Examiner also suggested that because Metcalf indicates that the optimum dose is 25-30mg/day, a 10 mg dose would have been obvious "as it provides more options to patients" and speculated, without citing support, that adult patients might want to take one tablet three times a day or three tablets once a day.

Applicant's response

In response, applicant respectfully traverses the Examiner's rejection.

Applicant notes that there is no "three times a day" regimen mentioned in Metcalf or in the remainder of the combination of references. Metcalf discloses a one-time a day regimen (see page 60). Based on a 25mg-30mg per day dose, and the one-time a day

regimen disclosed by Metcalf, as well as art-recognized problems of (1) patient compliance and (2) pill-burden, a 10mg dosage form is clearly not obvious.

The idea that three tablets a day is obvious because it "provides more options to patients" is unsupported speculation and flies in the face of patient compliance and pill-burden problems. Notably, the Examiner has addressed neither patient compliance nor pill-burden.

Moreover, the Examiner has not addressed why the 10mg dosage form species would be obvious over the prior art as compared to any other dosage forms such as 1mg, 2mg, 5mg, 25mg, 30mg etc. In fact, the Examiner is not following MPEP §2144.08 which requires of the Examiner that "[t]he fact-findings should specifically articulate what teachings or suggestions in the prior art would have motivated one of ordinary skill in the art to select the claimed species or subgenus". No such facts have been cited by the Examiner. In fact, in response to applicant's Declaration under 37 C.F.R. §1.132 by Dr. Faith Ottery provided as Exhibit 1 of applicants' Communication filed on May 15, 2008, which described, inter alia, pill burden and patient compliance problems suggesting against the Examiner's speculative and unsupported dosage regimes, the Examiner has simple declared the position set forth by applicant is "not persuasive for reasons set forth in the prior office action." Accordingly, the Examiner has also not followed MPEP §2145 which requires that "Office personnel should not evaluate rebuttal evidence for its 'knockdown' value against the prima facie case, *Piasecki*, 745 F.2d at 1473, 223 USPQ at 788, or summarily dismiss it as not compelling or insufficient. If the evidence is deemed insufficient to rebut the prima facie case of obviousness, Office personnel should specifically set forth the facts and reasoning

that justify this conclusion." (emphasis added). Simply dismissing the evidence provided in the Declaration under 37 C.F.R. §1.132 as not persuasive for *reasons set forth in a prior Office Action* does not amount to facts and reasoning that justifying the conclusion.

Accordingly, the Examiner has not made a proper Obviousness rejection and has maintained the rejection in a manner inconsistent with the guidance of MPEP §§2144.08 and 2145.

The Examiner has reconstructed applicant's claimed 10mg unit dose form by (a) selecting one of several possible daily doses daily doses from Metcalf, then (b) dividing it by an arbitrary *n*, where *n* = the number of times per day, to somehow arrive at the claimed invention, without any reasoned basis for arriving at *n*, other than that it fits speculative and unsupported patient dosage schedules.

Applicant maintains that for the reasons articulated herein and as supported in the Declaration under 37 C.F.R. §1.132 provided as Exhibit 1 of applicants' Communication filed on May 15, 2008 the invention as claimed is not obvious over the cited combination of prior art. Accordingly, applicant respectfully requests reconsideration and withdrawal of this ground of rejection.

If a telephone interview would be of assistance in advancing prosecution of the subject application, applicant's undersigned attorneys invite the Examiner to telephone them at the number provided below.

No fee, other than the enclosed total fee of $470.00, including a one-month extension of time fee of $65.00 and a $405.00 RCE fee is deemed necessary with the filing of this Amendment. However, if any additional fee is required, authorization is hereby given to charge the amount of such fee to Deposit Account No. 03-3125.

Respectfully submitted,

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I hereby certify that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to:

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Gary J. Gershik 5/6/09

Gary J. Gershik Date
Reg. No. 39,992

EXHIBIT A

U.S. Court of Appeals
Federal Circuit

Fujikawa v. Wattanasin

Nos. 95-1418 and 95-1425

Decided August 28, 1996

PATENTS

1. Patentability/Validity — Date of invention — Reduction to practice (§115.0405)

Board of Patent Appeals and Interferences did not err by finding that junior party in interference reduced chemical compound for inhibiting cholesterol biosynthesis to practice by in vitro testing, since positive in vitro results, in combination with known correlation between such in vitro results and in vivo activity, may be sufficient to establish practical utility, since board relied on testimony from those skilled in art that in vitro results convinced them that claimed compounds would exhibit desired pharmacological activity in vivo, and since evidence and testimony presented by senior party does not show absence of reliable relationship between in vitro and in vivo results for cholesterol inhibiting compounds.

2. Patentability/Validity — Date of invention — Suppression or concealment (§115.0407)

Junior party in interference did not intentionally suppress or conceal invention corresponding to counts for compound and method for inhibiting cholesterol biosynthesis, since intentional suppression requires evidence that inventor intentionally delayed filing in order to prolong period during which invention is maintained in secret, whereas evidence in present case shows that, throughout period between reduction to practice and filing, junior party and real party in interest moved slowly but inexorably toward disclosure.

3. Patentability/Validity — Date of invention — Suppression or concealment (§115.0407)

Evidence that first inventor was spurred to file patent application by activities of second inventor is important factor in priority determinations since it creates inference that, but for efforts of second inventor, public would never have gained knowledge of invention; in present case, no reasonable trier of fact could have found that junior party in interference was spurred to file by activities of third party, since attorney who drafted junior party's application expressly testified, without contradiction, that she had already begun work on draft application before learning of third party's patent.

4. Patentability/Validity — Date of invention — Suppression or concealment (§115.0407)

Delay of 17 months between reduction to practice and filing of application does not warrant finding that junior party in interference suppressed or concealed invention corresponding to interference counts, since total conduct of inventor, rather than elapsed time of delay, is controlling factor in deciding questions of suppression and concealment, and since disclosure-related activity of junior party inventor and real party in interest during much of delay period in present case is sufficient, in view of complexity of subject matter at issue, to avoid inference of suppression or concealment.

5. Patentability/Validity — Date of invention — Suppression or concealment (§115.0407)

Junior party in interference who carried out in vitro testing of compounds falling within scope of count, abandoned project but returned to it well before senior party's effective filing date, and worked diligently towards reducing invention to practice for second time, is not barred from relying on earliest date of renewed activity for purposes of priority, since any inference of suppression or concealment arising from delay between first alleged reduction to practice and filing of application is negated by junior party's renewed activity prior to senior party's effective filing date.

6. Practice and procedure in Patent and Trademark Office — Interference — Counts (§110.1703)

Patentability/Validity — Specification — Written description (§115.1103)

Board of Patent Appeals and Interferences did not clearly err by denying motion of senior party to add sub-genus count to interference on ground that proposed count is not sufficiently described by junior party's disclosure of compound for inhibiting cholesterol biosynthesis, since proposed sub-genus is not disclosed ipsis verbis by junior party, since junior party's application contains no indications as to what compounds, other than those disclosed as preferred, might be of special interest, and since, absent such indications, simply describing large genus of compounds is not sufficient to satisfy written description requirement as to particular species or sub-genus.

7. Practice and procedure in Patent and Trademark Office — Interference — Counts (§110.1703)

Patentability/Validity — Specification — Written description (§115.1103)

Application of junior party in interference pertaining to compound for inhibiting cholesterol biosynthesis does not provide adequate direction which reasonably would lead persons skilled in art to sub-genus of count proposed by senior party, even though proposed count recites at least one of junior party's preferred choices with respect to practically every position on compound, since proposed sub-genus diverges from junior party's preferred elements with respect to at least one position, and although substitution suggested for that position by senior party might seem simple and foreseeable in hindsight, junior party's disclosure provides no indication that said position would be better candidate for substitution than any other.

Appeal from the U.S. Patent and Trademark Office, Board of Patent Appeals and Interferences.

Two related interferences between senior party Yoshihiro Fujikawa, Mikio Suzuki, Hiroshi Iwasaki, Mitsuaki Sakashita, and Masaki Kitahara, and junior party Sompong Wattanasin. From decisions granting priority of invention to junior party in both proceedings, and denying senior party's motion to add additional count to interferences, senior party appeals. Affirmed.

Steven B. Kelber, of Oblon, Spivak, McClelland, Maier & Neustadt, Arlington, Va., for appellants.

Diane E. Furman, of Sandoz Corp., East Hanover, N.J., for appellee.

Before Mayer, Clevenger, and Rader, circuit judges.

Clevenger, J.

Yoshihiro Fujikawa et al (Fujikawa) appeal from two decisions of the Board of Patent Appeals and Interferences of the United States Patent & Trademark Office (Board) granting priority of invention in two related interferences to Sompong Wattanasin, and denying Fujikawa's motion to add an additional sub-genus count to the interferences. We affirm.

I

These interferences pertain to a compound and method for inhibiting cholesterol biosynthesis in humans and other animals. The compound count recites a genus of novel mevalonolactones. The method count recites a method of inhibiting the biosynthesis of cholesterol by administering to a "patient in need of said treatment" an appropriate dosage of a compound falling within the scope of the compound count.

The real parties in interest are Sandoz Pharmaceuticals Corporation (Sandoz), assignee of Wattanasin, and Nissan Chemical Industries, Ltd. (Nissan), assignee of Fujikawa.

The inventive activity of Fujikawa, the senior party, occurred overseas. Fujikawa can thus rely only on his effective filing date, August 20, 1987, to establish priority. 35 U.S.C. § 102(g) (1994). Whether Wattanasin is entitled to priority as against Fujikawa therefore turns on two discrete questions. First, whether Wattanasin has shown conception coupled with diligence from just prior to Fujikawa's effective filing date until reduction to practice. *Id.* Second, whether Wattanasin suppressed or concealed the invention between reduction to practice and filing. *Id.* With respect to the first question, Fujikawa does not directly challenge the Board's holdings on Wattanasin's conception or diligence, but rather contends that the Board incorrectly fixed the date of Wattanasin's reduction to practice. As for the second question, Fujikawa contends that the Board erred in concluding that Wattanasin had not suppressed or concealed the invention. Fujikawa seeks reversal, and thus to establish priority in its favor, on either ground.

II

The Board divided Wattanasin's inventive activity into two phases. The first phase commenced in 1979 when Sandoz began searching for drugs which would inhibit the biosynthesis of cholesterol. Inventor Wattanasin was assigned to this project in 1982, and during 1984-1985 he synthesized three compounds falling within the scope of the compound count. When tested *in vitro*, each of these compounds exhibited some cholesterol-inhibiting activity, although not all the chemicals were equally effective. Still, according to one Sandoz researcher, Dr. Damon, these test results indicated that, to a high probability, the three compounds "would be active when administered *in vivo* to a patient to inhibit cholesterol biosynthe-

sis, i.e. for the treatment of hypercholesteremia or atherosclerosis." Notwithstanding these seemingly positive results, Sandoz shelved Wattanasin's project for almost two years, apparently because the level of *in vitro* activity in two of the three compounds was disappointingly low.

By January 1987, however, interest in Wattanasin's invention had revived, and the second phase of activity began. Over the next several months, four more compounds falling within the scope of the compound count were synthesized. In October, these compounds were tested for *in vitro* activity, and each of the four compounds yielded positive results. Again, however, there were significant differences in the level of *in vitro* activity of the four compounds. Two of the compounds in particular, numbered 64-935 and 64-936, exhibited *in vitro* activity significantly higher than that of the other two compounds, numbered 64-933 and 64-934.

Soon after, in December 1987, the three most active compounds *in vitro* were subjected to additional *in vivo* testing. For Sandoz, one primary purpose of these tests was to determine the *in vivo* potency of the three compounds relative to that of Compactin, a prior art compound of known cholesterol-inhibiting potency. From the results of the *in vivo* tests, reproduced in the margin,[1] Sandoz calculated an ED50 [2] for each of the compounds and compared it to the ED50 of Compactin. Only one of the compounds, compound 64-935, manifested a better ED50 than Compactin: an ED50 of 0.49 as compared to Compactin's ED50 of 3.5. All of the tests performed by Sandoz were conducted in accordance with established protocols.

During this period, Sandoz also began to consider whether, and when, a patent application should be filed for Wattanasin's invention. Several times during the second phase of activity, the Sandoz patent committee considered the question of Wattanasin's invention but decided that it was too early in the invention's development to file a patent application. Each time, however, the patent committee merely deferred decision on the matter and specified that it would be taken up again at subsequent meetings. Finally, in January 1988, with the *in vivo* testing completed, the Committee assigned Wattanasin's invention an "A" rating which meant that the invention was ripe for filing and that a patent application should be prepared. The case was assigned to a Ms. Geisser, a young patent attorney in the Sandoz patent department with little experience in the pharmaceutical field.

Over the next several months the Sandoz patent department collected additional data from the inventor which was needed to prepare the patent application. This data gathering took until approximately the end of May 1988. At that point, work on the case seems to have ceased for several months until Ms. Geisser began preparing a draft sometime in the latter half of 1988. The parties dispute when this preparation began. Fujikawa contends that it occurred as late as October, and that Ms. Geisser was spurred to begin preparing the draft application by the discovery that a patent to the same subject matter had been issued to a third party, Picard. Fujikawa, however, has no evidence to support that contention. In contrast, Sandoz contends that Ms. Geisser began the draft as early as August, and that she was already working on the draft when she first heard of Picard's patent. The evidence of record, and in particular the testimony of Ms. Geisser, supports that version of events. In any event, the draft was completed in November and, after several turn-arounds

[1]

Compound	dosage	% change
64-933	1.0	-36.3%
	0.3	-17.0%
	0.1	-18.6%
64-935	1.0	-65.8%
	0.3	-29.7%
	0.1	-36.3%
64-936	1.0	-9.0%
	0.3	-39.2%
	0.1	-22.5%

[2] The ED50 of a compound represents the effective concentration, measured in milligrams of compound per kilogram of laboratory specimen, which inhibits cholesterol biosynthesis by 50%.

with the inventor, ultimately filed in March of 1989.

Both Wattanasin and Fujikawa requested an interference with Picard. The requests were granted and a three-party interference between Picard, Fujikawa, and Wattanasin was set up. Early in the proceedings, however, Picard filed a request for an adverse judgment presumably because he could not antedate Fujikawa's priority date. What remained was a two-party interference between Fujikawa and Wattanasin. Ultimately, for reasons not significant to this appeal, the interference was divided into two interferences: one relating to the method count and one relating to the compound count. The Board decided each of these interferences adverse to Fujikawa.

With respect to the compound count, the Board made two alternative findings regarding reduction to practice. First, it found that the *in vitro* results in October 1987 showed sufficient practical utility for the compound so as to constitute a reduction to practice as of the date of those tests.[1] In the alternative, the Board held, the *in vivo* tests which showed significant activity in the 64-935 compound at doses of 1.0 and 0.1 mg were sufficient to show practical utility. Consequently, Wattanasin had reduced the compound to practice, at the latest, as of December 1987. Since Fujikawa did not challenge Wattanasin's diligence for the period between Fujikawa's effective filing date of August 20, 1987 and Wattanasin's reduction to practice in either October or December 1987, the Board held that Wattanasin was *de facto* the first inventor of the compound count. Finally, the Board found that the seventeen month period (counting from the *in vitro* testing) or fifteen month period (counting from the *in vivo* testing) between Wattanasin's reduction to practice and filing was not sufficient to raise an inference of suppression or concealment given the complexity of the invention, and therefore awarded priority of the compound count to Wattanasin. In reaching this conclusion, the Board rejected Fujikawa's argument that Wattanasin was spurred to file by Picard because it held that spurring by Picard, a third party, had no legal effect in a priority dispute between Fujikawa and Wattanasin.

With respect to the method count, the Board determined that Wattanasin reduced to practice in December 1987 on the date that *in vivo* testing of the 64-935 compound was concluded. In reaching that conclusion, the Board first noted that a reduction to practice must include every limitation of the count. Consequently, Wattanasin's early *in vitro* testing could not constitute a reduction to practice of the *method* count, since that count recites administering the compound to a "patient." The *in vivo* testing, however, met the limitations of the count since the word "patient" was sufficiently broad to include the laboratory rats to whom the compounds were administered. The *in vivo* testing also proved that 64-935 had practical utility because the compound displayed significant cholesterol inhibiting activity at doses of 1.0 and 0.1 mg. Given this date of reduction to practice, the Board again held that Wattanasin was the *de facto* first inventor of the count and that the delay in filing of fifteen months was not sufficient to trigger an inference of suppression or concealment. The Board therefore awarded priority of the method count to Wattanasin.

Before this court, Fujikawa seeks review of these adverse priority determinations. In addition, during the motions period of the interference, Fujikawa moved to have an additional sub-genus count added to the interference. The Board denied that motion on the ground that the Wattanasin disclosure did not contain a sufficient written description to support the proposed count. Fujikawa appeals that decision, as well. We have jurisdiction to hear this appeal under 28 U.S.C. § 1295(a)(4)(A) (1994).

III

We first address Fujikawa's argument that Wattanasin's *in vitro* and *in vivo* tests failed to establish a practical utility for either the compound or method count. The Board held that the *in vitro* tests established a practical utility for the compound and that the *in vivo* tests established a practical utility for both the compound and method counts. For the reasons set out below, we affirm these findings of the Board.

For over 200 years, the concept of utility has occupied a central role in our patent system. *See Brenner v. Manson*, 383 U.S. 519, 529, 148 USPQ 689, 693 (1966). Indeed, "[t]he basic *quid pro quo* contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility." *Id.* at 534, 148 USPQ at 695. Consequently, it is well established that a patent may not be granted to an invention

[1] As explained more fully below, reduction to practice requires a showing of practical utility, which may be satisfied by an "adequate showing of any pharmacological activity." *Nelson v. Bowler*, 626 F.2d 853, 856, 206 USPQ 881, 883 (CCPA 1980).

unless substantial or practical utility for the invention has been discovered and disclosed. *See Cross v. Iizuka*, 753 F.2d 1040, 1044, 224 USPQ 739, 742 (Fed. Cir. 1985). Similarly, actual reduction to practice, which constitutes in law the final phase of invention, cannot be established absent a showing of practical utility. *See Blicke v. Treves*, 241 F.2d 718, 720-21, 112 USPQ 472, 474-75 (CCPA 1957).

In the pharmaceutical arts, our court has long held that practical utility may be shown by adequate evidence of any pharmacological activity. *See, e.g., Nelson v. Bowler*, 626 F.2d 853, 856, 206 USPQ 881, 883 (CCPA 1980); *In re Krimmel*, 292 F.2d 948, 952-53, 130 USPQ 215, 219 (CCPA 1961). For example, in *Campbell v. Wettstein*, 476 F.2d 642, 646-47, 177 USPQ 376, 379 (C.C.P.A. 1973) we stated that "[m]oreover, the interference counts contain no limitation relating to intended use or to discovered properties of the claimed compounds. Accordingly, under well-established precedent, evidence establishing substantial utility for any purpose is sufficient to show reduction to practice." The rule in *Campbell* was applied in *Rey-Bellet v. Engelhardt*, 493 F.2d 1380, 1383, 181 USPQ 453, 454 (C.C.P.A. 1974) ("Since the count contains no limitation related to any utility, evidence which would establish a substantial utility for any purpose is sufficient to show its reduction to practice.").[4] Such activity constitutes a practical utility because "[i]t is inherently faster and easier to combat illnesses and alleviate symptoms when the medical profession is armed with an arsenal of chemicals having known pharmacological activities. Since it is crucial to provide researchers with an incentive to disclose pharmacological activities in as many compounds as possible, we conclude that adequate proof of any such activity constitutes a showing of practical utility." *Nelson*, 626 F.2d at 856, 206 USPQ at 883; *see also Krimmel*, 292 F.2d at 952-53, 130 USPQ at 219.

It may be difficult to predict, however, whether a novel compound will exhibit pharmacological activity, even when the behavior of analogous compounds is known to those skilled in the art. Consequently, testing is often required to establish practical utility. *See, e.g., Blicke*, 241 F.2d at 720, 112 USPQ at 475. But the test results need not absolutely prove that the compound is pharmacologically active. All that is required is that the tests be "*reasonably* indicative of the desired [pharmacological] response." *Nelson*, 626 F.2d at 856, 206 USPQ at 884. (emphasis added). In other words, there must be a sufficient correlation between the tests and an asserted pharmacological activity so as to convince those skilled in the art, to a reasonable probability, that the novel compound will exhibit the asserted pharmacological behavior. *See Cross*, 753 F.2d at 1050, 224 USPQ at 747.

The ultimate determination of reduction to practice is a question of law which we review de novo. *See Holmwood v. Sugavanam*, 948 F.2d 1236, 1238, 20 USPQ2d 1712, 1714 (Fed. Cir. 1991). In contrast, we review the Board's factual findings supporting its legal conclusions about reduction to practice for clear error. *Id.* Whether a practical utility has been established for a novel compound is a question of fact. *See Cross*, 753 F.2d at 1044 n.7, 224 USPQ at 742 n.7. We therefore review the Board's findings with respect to practical utility for clear error.

A

This court has, on many occasions, considered the type and quantity of testing necessary to establish a practical utility for a novel compound. Although each case of practical utility must be considered on its own facts, *see, e.g., Blicke*, 241 F.2d at 720, 112 USPQ at 475, examination of our precedent illustrates the degree of proof which we have deemed sufficient to establish practical utility in the past.

[1] The facts in this case are substantially similar to those in *Cross v. Iizuka*, 753 F.2d 1040, 224 USPQ 739 (Fed. Cir. 1985). There, we expressly held that, in appropriate circumstances, evidence of *in vitro* testing could adequately establish a practical utility.[5] As we there explained:

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[4] Strictly speaking, this articulation of the standard (i.e. evidence of *any* pharmacological activity) applies only when the count does not recite a particular utility. *See Rey-Bellet v. Engelhardt*, 493 F.2d 1380, 1383, 181 USPQ 453, 454 (CCPA 1974). In contrast, when the count recites a particular utility, practical utility requires an adequate showing of the recited utility. In this case, the compound count does not recite a particular utility, and practical utility is thus satisfied by evidence of any pharmacological activity. The method count, however, does recite a particular utility (i.e., cholesterol inhibition in patients in need of such treatment), and practical utility for that count therefore requires an adequate showing of that recited utility.

[5] While *Cross* involved a constructive reduction to practice, the same general principles are applicable to an actual reduction to practice. *See id.* at 1046 n.14, 224 USPQ at 744 n.14.

> We perceive no insurmountable difficulty, under appropriate circumstances, in finding that the first link in the screening chain, *in vitro* testing, may establish a practical utility for the compound in question. . . . [U]nder the circumstances of the instant case, where [an application] discloses an *in vitro* utility, . . . and where the disclosed *in vitro* utility is supplemented by the similar *in vitro* and *in vivo* pharmacological activity of structurally similar compounds, . . . we agree with the Board that this *in vitro* utility is sufficient to [establish utility].

Id. at 1051, 224 USPQ at 748. Thus, *Cross* holds that positive *in vitro* results, in combination with a known correlation between such *in vitro* results and *in vivo* activity, may be sufficient to establish practical utility.

Fujikawa does not argue that the law as stated in *Cross* is incorrect. Instead, Fujikawa contends that Wattanasin has failed to establish an adequate correlation between *in vitro* and *in vivo* results in the field of cholesterol-inhibiting compounds to permit Wattanasin to rely on affirmative *in vitro* results to establish a practical utility for the compound.

The Board determined that Wattanasin had reduced the compound count to practice in October 1987 when several compounds falling within the scope of the genus count exhibited activity *in vitro*. In reaching that conclusion, the Board relied on testimony from those skilled in the art that the *in vitro* results convinced them that the claimed compounds would exhibit the desired pharmacological activity when administered *in vivo*. This included testimony that "*in vivo* activity is typically highly correlatable to a compound's *in vitro* activity" in this field. The facts in this case are thus analogous to the ones in *Cross* where the court relied on positive *in vitro* test results in combination with a known correlation between such *in vitro* tests and *in vivo* activity to support a finding of practical utility.

To counter the Board's decision, Fujikawa points to the testimony of its own expert, Dr. Holmlund, who testified that:

> there is a reasonable element of doubt that some elements may be encountered which are active in the *in vitro* assay, but yet inactive in the *in vivo* assay.

According to Fujikawa, this testimony establishes that the *in vitro* tests were insufficient to prove practical utility.

We note first that to the extent the record presents a conflict in the testimony, the Board was well within its discretion as fact finder to credit the testimony of Wattanasin's witnesses over that of Fujikawa's. More fundamentally, however, we do not consider Dr. Holmlund's testimony as a whole to contradict the Board's finding. Of course, it is possible that some compounds active *in vitro* may not be active *in vivo*. But, as our predecessor court in *Nelson* explained, a "rigorous correlation" need not be shown in order to establish practical utility; "reasonable correlation" suffices. Here, even Dr. Holmlund implied in the question and answer immediately following the above quoted portion of his testimony, that such a "reasonable correlation" exists:

> Q. Would you accept, subject to exceptions that might occur, that the failure to find [*in vivo*] activity would be considered an exception, that there would be a reasonable expectancy [that *in vitro* activity implies that the compound will be active *in vivo*]?
>
> A. I think I would probably accept that.

Fujikawa also cites two articles [6] which it claims show that there is no reliable relationship between *in vitro* results and *in vivo* results in cholesterol inhibiting compounds similar to the ones at issue in this case. We disagree. Although the Sliskovic article, for example, teaches that *in vitro* testing is sometimes not a good indicator of how potent a compound will be *in vivo*, it does imply that compounds which are active *in vitro* will normally exhibit some *in vivo* activity. *See* Sliskovic, at 370. Similarly, the Kathawala article expressly states: "For most substances, although not for all, the relative potency determined in *in vitro* microsomal assay against HMG-CoA reductase parallels the *in vivo* activity in rats for the inhibition of 14C-acetate into sterols." Kathawala at 136-37. On these facts, we hold that the Board did not err in finding that Wattanasin's *in vitro* tests established a practical utility for the genus recited in the compound count.

B

Turning to the method count, the Board found that Wattanasin reduced the method to practice in December 1987 when successful *in vivo* testing of the compound was completed. This finding, too, was based on

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[6] The two articles are D.R. Sliskovic et al, *Inhibitors of Cholesterol Biosynthesis*, 34 J. Med. Chemistry 367 (1991) (Sliskovic); and F.G. Kathawala, *HMG-CoA Reductase Inhibitors: An Exciting Development in the Treatment of Hyperlipoproteinemia*, 11 Medicinal Research Reviews 121 (1991) (Kathawala).

testimony that the *in vivo* data for one of the compounds tested, 64-935, showed significant cholesterol inhibiting activity in the laboratory rats tested.

Fujikawa challenges the Board's holding by referring to an anomaly in the test data of the 64-935 compound which it contends undercuts the reliability of the *in vivo* tests. In particular, Fujikawa points to the fact that the compound's potency was less at a dosage of 0.3 mg than it was at a dosage of 0.1 mg. On the basis of this aberration, Fujikawa's expert, Dr. Holmlund, testified that this test data was unreliable and could not support a finding that the compound was pharmacologically active.

It is clear from the Board's opinion, however, that to the extent Dr. Holmlund was testifying that this aberration would lead one of ordinary skill to completely reject these test results, the Board did not accept his testimony. This decision of the Board was not clear error. Admittedly, the decreased potency at 0.3 mg is curious. The question remains, however, as to how much this glitch in the data would undercut the persuasiveness of the test results as a whole in the mind of one of ordinary skill. Each party presented evidence on this point and the Board resolved this disputed question of fact by finding that the test results as a whole were sufficient to establish pharmacological activity in the minds of those skilled in the art. In doing so, the Board properly exercised its duty as fact finder, and we therefore affirm its finding on this point.[7]

As noted above, Fujikawa does not challenge the Board's conclusions that Wattanasin conceived prior to Fujikawa's effective date or that Wattanasin pursued the invention with diligence from just prior to Fujikawa's date until his reductions to practice in October and December 1987. Consequently, we affirm the Board's finding that Wattanasin has shown conception coupled with diligence from just prior to Fujikawa's effective date of August 20, 1987 up to the date he reduced the invention to practice in October 1987, for the compound, or December 1987, for the method.

IV

Having determined that Wattanasin was the *de facto* first inventor, the remaining question before the Board was whether Wattanasin had suppressed or concealed the invention between the time he reduced to practice and the time he filed his patent application. Suppression or concealment of the invention by Wattanasin would entitle Fujikawa to priority. 35 U.S.C. § 102(g).

Suppression or concealment is a question of law which we review de novo. *Brokaw v. Vogel*, 429 F.2d 476, 480, 166 USPQ 428, 431 (CCPA 1970). Our case law distinguishes between two types of suppression and concealment: cases in which the inventor deliberately suppresses or conceals his invention, and cases in which a legal inference of suppression or concealment is drawn based on "too long" a delay in filing a patent application. *Paulik v. Rizkalla*, 760 F.2d 1270, 1273, 226 USPQ 224, 226 (Fed. Cir. 1985) (in banc).

[2] Fujikawa first argues that there is evidence of intentional suppression or concealment in this case. Intentional suppression refers to situations in which an inventor "designedly, and with the view of applying it indefinitely and exclusively for his own profit, withholds his invention from the public." *Id.* (quoting *Kendall v. Winsor*, 62 U.S. (21 How.) 322, 328 (1858)). Admittedly, Sandoz was not overly efficient in preparing a patent application, given the time which elapsed between its reduction to practice in late 1987 and its ultimate filing in March 1989. Intentional suppression, however, requires more than the passage of time. It requires evidence that the inventor intentionally delayed filing in order to prolong the period during which the invention is main-

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[7] Before the Board, Fujikawa additionally argued that *in vivo* testing cannot establish reduction to practice of the method count because it does not fulfill every limitation of the count. In particular, Fujikawa argued that only human beings can be considered "patients in need of" cholesterol biosynthesis inhibition, as required by the count. As noted above, the Board rejected this argument and held that the term "patient" in the count is broad enough to encompass mammals, such as the laboratory rats tested *in vivo*.

In its brief to this court, Fujikawa renews this argument. In the process, however, Fujikawa seems to add an additional ground which it did not argue before the Board below. We are not absolutely certain, but it appears that Fujikawa is now contending that *in vivo* testing cannot constitute a reduction to practice because the rats tested were, from all that would appear, healthy animals, rather than animals in need of cholesterol biosynthesis inhibition. To the extent that Fujikawa's argument before this court is directed to this novel ground not raised below, we consider the argument waived and decline to address it. To the extent that Fujikawa is still arguing that the count requires administration of the compound to a human, we disagree, and affirm the Board's decision on this point.

tained in secret. *Cf. Peeler v. Miller*, 535 F.2d 647, 653-54, 190 USPQ 117, 122 (CCPA 1976) (implying that intentional suppression requires showing of specific intent). Fujikawa presented no evidence that Wattanasin delayed filing for this purpose. On the contrary, all indications are that throughout the period between reduction to practice and filing, Sandoz moved slowly (one might even say fitfully), but inexorably, toward disclosure. We therefore hold that Wattanasin did not intentionally suppress or conceal the invention in this case.

[3] Absent intentional suppression, the only question is whether the 17 month period between the reduction to practice of the compound, or the 15 month period between reduction to practice of the method, and Wattanasin's filing justify an *inference* of suppression or concealment. *See id.* The Board held that these facts do not support such an inference. As the Board explained: "In our view, this hiatus in time is not sufficiently long to raise the inference that Wattanasin suppressed or concealed the invention considering the nature and complexity of the invention here." Fujikawa attacks this finding of the Board on two grounds. First, it contends that the Board should not have held that a 15 or 17 month delay is *per se* insufficient to raise an inference of suppression or concealment without examining the circumstances surrounding the delay and whether, in view of those circumstances, Wattanasin's delay was reasonable. Second, Fujikawa argues that the Board failed to consider evidence that Wattanasin was spurred to file by the issuance of a patent to a third party, Picard, directed to the same genus of compounds invented by Wattanasin. Evidence that a first inventor was spurred to disclose by the activities of a second inventor has always been an important factor in priority determinations because it creates an inference that, but for the efforts of the second inventor, "the public would never have gained knowledge of [the invention]." *Brokaw*, 429 F.2d at 480, 166 USPQ at 431. Here, however, the Board expressly declined to consider the evidence of spurring because it held that spurring by a third party who is not a party to the interference is irrelevant to a determination of priority as between Wattanasin and Fujikawa. We first address Fujikawa's arguments concerning spurring.

A

We are not certain that the Board is correct that third party spurring is irrelevant in determining priority. After all, "[w]hat is involved here is a policy question as to which of the two rival inventors has the greater right to a patent." *Brokaw*, 429 F.2d at 480, 166 USPQ at 430. Resolution of this question could well be affected by the fact that one of the inventors chose to maintain his invention in secrecy until disclosure by another spurred him to file, even when the spurrer was a third party not involved in the interference. We need not resolve that question here, however, because we hold that no reasonable fact finder could have found spurring on the facts of this case. The only evidence in the record on the question of spurring is the testimony of Ms. Geisser who expressly testified that she had already begun work on the Wattanasin draft application before she learned of Picard's patent, in other words, that she had not been spurred by Picard. Consequently, we leave the question of the relevance of third party spurring for another case.

B

Fujikawa's other argument also requires us to examine the evidence of record in this case. As Fujikawa correctly notes, this court has not set strict time limits regarding the minimum and maximum periods necessary to establish an inference of suppression or concealment. *See Correge v. Murphy*, 705 F.2d 1326, 1330, 217 USPQ 753, 756 (Fed. Cir. 1983). Rather, we have recognized that "it is not the time elapsed that is the controlling factor but the total conduct of the first inventor." *Young v. Dworkin*, 489 F.2d 1277, 1285, 180 USPQ 388, 395 (CCPA 1974) (Rich, J., concurring). Thus, the circumstances surrounding the first inventor's delay and the reasonableness of that delay are important factors which must be considered in deciding questions of suppression or concealment. *See, e.g., id.* at 1281-82, 180 USPQ at 392-93. Fujikawa again correctly notes that the Board's opinion gives short shrift to the question of whether *this* delay on the facts of *this* case was reasonable. In seeking reversal of the Board's decision, Fujikawa asks us to assess the factual record for ourselves to determine whether Wattanasin engaged in sufficient disclosure-related activity to justify his 17-month delay in filing. The facts of record, however, do not support Fujikawa's position.

[4] In our view, the circumstances in this case place it squarely within the class of cases in which an inference of suppression or concealment is not warranted. We acknowledge, of course, that each case of suppression or concealment must be decided on its own facts. Still, the rich and varied case law

which this court has developed over many years provides some guidance as to the type of behavior which warrants an inference of suppression or concealment. *See Paulik*, 760 F.2d at 1280, 226 USPQ at 231-32 (Rich, J., concurring). In this case Wattanasin delayed approximately 17 months between reduction to practice and filing. During much of that period, however, Wattanasin and Sandoz engaged in significant steps towards perfecting the invention and preparing an application. For example, we do not believe any lack of diligence can be ascribed to Wattanasin for the period between October and December 1987 when *in vivo* testing of the invention was taking place. *See Young*, 489 F.2d at 1281, 180 USPQ at 392. Similarly, at its first opportunity following the *in vivo* testing, the Sandoz patent committee approved Wattanasin's invention for filing. This takes us up to the end of January 1988.

Over the next several months, until May 1988, the Sandoz patent department engaged in the necessary collection of data from the inventor and others in order to prepare Wattanasin's patent application. We are satisfied from the record that this disclosure-related activity was sufficient to avoid any inference of suppression or concealment during this period.[8] *Cf. Correge*, 705 F.2d at 1330-31, 217 USPQ at 756 (five significant acts of disclosure-related activity over the course of seven months sufficient to rebut any inference of suppression). Also, as noted above, the record indicates that by August 1988, Ms. Geisser was already at work preparing the application, and that work continued on various drafts until Wattanasin's filing date in March 1989. Thus, the only real period of unexplained delay in this case is the approximately three month period between May and August of 1988.

Given a total delay of 17 months, an unexplained delay of three months, the complexity of the subject matter at issue, and our sense from the record as a whole that throughout the delay Sandoz was moving, albeit slowly, towards filing an application, we conclude that this case does not warrant an inference of suppression or concealment. Consequently, we affirm the Board on this point.

C

Finally, Fujikawa contends that assuming *in vitro* tests are sufficient to establish reduction to practice, Wattanasin reduced the compound count to practice in 1984 when he completed *in vitro* testing of his first three compounds falling within the scope of the count. If so, Fujikawa argues, the delay between reduction to practice and filing was greater than four years, and an inference of suppression or concealment is justified.[9]

[5] We reject this argument in view of *Paulik v. Rizkalla*, 760 F.2d 1270, 226 USPQ 224 (Fed. Cir. 1985) (in banc). In *Paulik*, we held that a suppression or concealment could be negated by renewed activity prior to an opposing party's effective date. There, inventor Paulik reduced his invention to practice and submitted an invention disclosure to his employer's patent department. For four years the patent department did nothing with the disclosure. Then, just two months before Rizkalla's effective date, the patent department allegedly picked up Paulik's disclosure and worked diligently to prepare a patent application which it ultimately filed. *See id.* at 1271-72, 226 USPQ at 224-25. We held that although Paulik could not rely on his original date of reduction to practice to establish priority, he could rely on the date of renewed activity in his priority contest with Rizkalla. In large measure, this decision was driven by the court's concern that denying an inventor the benefit of his renewed activity, might "discourage inventors and their supporters from working on projects that had been 'too long' set aside, because of the impossibility of relying, in a priority contest, on either their original work or their renewed work." *Id.* at 1275-76, 226 USPQ at 227-28.

Paulik's reasoning, if not its holding, applies squarely to this case. A simple hypothetical illustrates why this is so. Imagine a situation similar to the one facing Sandoz in early 1987. A decisionmaker with limited funds must decide whether additional research funds should be committed to a project which has been neglected for over two years. In making this decision, the decisionmaker would certainly take into account the likelihood that the additional research might

[8] Our conclusion in this regard is based, in small part, on the testimony of Mr. Melvyn Kassenoff, a lawyer in Sandoz's patent department. Before the Board, Fujikawa challenged large parts of this testimony as inadmissible. In this opinion we therefore rely only on those portions of the testimony which even Fujikawa concedes are admissible, i.e., testimony relating to Mr. Kassenoff's legal services rendered in connection with the prosecution of Wattanasin's application.

[9] This argument, of course, relates only to the compound count, since, as explained above, the method count was not reduced to practice until the *in vivo* testing in December 1987.

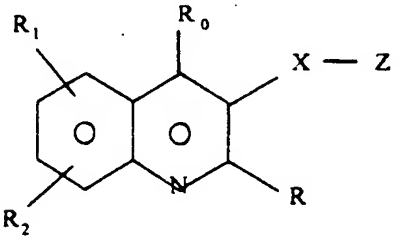
yield valuable patent rights. Furthermore, in evaluating the probability of securing those patent rights, an important consideration would be the earliest priority date to which the research would be entitled, especially in situations where the decisionmaker knows that he and his competitors are "racing" toward a common goal. Thus, the right to rely on renewed activity for purposes of priority would encourage the decisionmaker to fund the additional research. Conversely, denying an inventor the benefit of renewed activity would discourage the decisionmaker from funding the additional research.

Here, Wattanasin returned to his abandoned project well before Fujikawa's effective date and worked diligently towards reducing the invention to practice a second time. For the reasons explained above, we hold that, on these facts, Wattanasin's earlier reduction to practice in 1984 does not bar him from relying on his earliest date of renewed activity for purposes of priority.

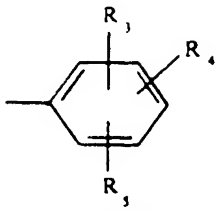
V

Fujikawa also appeals the Board's decision denying Fujikawa's motion to add a sub-genus count to the interference. The Board denied the motion because it found that Wattanasin's disclosure did not sufficiently describe Fujikawa's proposed count. Whether a disclosure contains a sufficient written description to support a proposed count, is a question of fact which we review for clear error. *Ralston Purina Co. v. Far-Mar-Co, Inc.*, 772 F.2d 1570, 1575, 227 USPQ 177, 179 (Fed. Cir. 1985). We affirm the Board's denial of Fujikawa's motion because we do not believe it was clearly erroneous.

Wattanasin's application disclosed compounds of the following structure:



wherein each of R and R_0 is, independently, C_{1-6} alkyl (primary, secondary, or tertiary), C_{3-7} cycloalkyl, or the following ring,



and each of R_1, R_2, R_3, R_4, and R_5 is, independently, hydrogen, C_{1-4}alkyl, C_{1-4}alkoxy, trifluoromethyl, fluoro, chloro, phenoxy, benzyloxy, or hydroxy.

In addition to this genus of compounds, Wattanasin disclosed as his preferred embodiments that: R_1 and R_2 are most preferably hydrogen, R_0 is most preferably phenyl, 4-fluorophenyl, or 3,5-dimethylphenyl; and R is most preferably methyl [10] or isopropyl.[11]

Essentially, Fujikawa's proposed sub-genus is directed to compounds of the above structure in which R is cyclopropyl [12] and R_0 is 4-fluorophenyl. In other respects, the parties do not dispute that the particular constituents recited in Fujikawa's proposed count are adequately disclosed in Wattanasin's application. Thus, for example, both Wattanasin's most preferred embodiment and Fujikawa's proposed count describe R_1 and R_2 as hydrogen.

In denying Fujikawa's motion, the Board first noted that the proposed sub-genus was not disclosed *ipsis verbis* by Wattanasin. Specifically, the Board noted that Wattanasin preferred methyl and isopropyl for R, rather than cyclopropyl as in the proposed count. In addition, Wattanasin listed three preferred choices for R_0 only one of which was 4-fluorophenyl and gave no indication in his application as to whether he would prefer any one of the choices over the other two.

As the Board recognized, however, *ipsis verbis* disclosure is not necessary to satisfy the written description requirement of section 112. Instead, the disclosure need only reasonably convey to persons skilled in the art that the inventor had possession of the subject matter in question. *In re Edwards*, 568 F.2d 1349, 1351-52, 196 USPQ 465, 467 (CCPA 1978). In other words, the question is whether Wattanasin's "application provides adequate direction which reasonably [would lead] persons skilled in the art" to the sub-genus of the proposed count. *Id.* at 1352, 196 USPQ at 467.

[10] Methyl is another name for C_1 alkyl.
[11] isopropyl is another name for C_3 alkyl.
[12] cyclopropyl is another name for C_3 cycloalkyl. and R_0 is 4-fluorophenyl.

> Many years ago our predecessor court graphically articulated this standard by analogizing a genus and its constituent species to a forest and its trees. As the court explained:
>
> It is an old custom in the woods to mark trails by making blaze marks on the trees. It is no help in finding a trail . . . to be confronted simply by a large number of unmarked trees. Appellants are pointing to trees. We are looking for blaze marks which single out particular trees. We see none.

In re Ruschig, 379 F.2d 990, 994-95, 154 USPQ 118, 122 (CCPA 1967).

[6] In finding that Wattanasin's disclosure failed to sufficiently describe the proposed sub-genus, the Board again recognized that the compounds of the proposed count were not Wattanasin's preferred, and that his application contained no blazemarks as to what compounds, other than those disclosed as preferred, might be of special interest. In the absence of such blazemarks, simply describing a large genus of compounds is not sufficient to satisfy the written description requirement as to particular species or sub-genuses. *See, e.g., id.* at 994, 154 USPQ at 122 ("Specific claims to single compounds require reasonably specific supporting disclosure and while . . . *naming* [each species] is not essential, something more than the disclosure of a class of 1000, or 100, or even 48 compounds is required.").

Before this court, Fujikawa challenges the Board's denial of its motion on two grounds. First, Fujikawa persists in arguing that its proposed count is disclosed *ipsis verbis* in Wattanasin's application. The basis for this contention seems to be that Wattanasin lists cyclopropyl as one possible moiety for R in his disclosure of the genus. Clearly, however, just because a moiety is listed as one possible choice for one position does not mean there is *ipsis verbis* support for every species or sub-genus that chooses that moiety. Were this the case, a "laundry list" disclosure of every possible moiety for every possible position would constitute a written description of every species in the genus. This cannot be because such a disclosure would not "reasonably lead" those skilled in the art to any particular species. We therefore reject Fujikawa's argument on this point.

Second, Fujikawa claims that the Board erred in finding that Wattanasin's disclosure contained insufficient blazemarks to direct one of ordinary skill to the compounds of its proposed count. Specifically, Fujikawa points out that with respect to practically every position on the compound, the proposed count recites at least one of Wattanasin's preferred choices. Even with respect to position R, Fujikawa further explains, one of ordinary skill would have been moved by Wattanasin's disclosure to substitute cyclopropyl for isopropyl because the two substituents are isosteric.

[7] While Fujikawa's arguments are not without merit, we cannot say, on this record, that the Board's decision was clearly erroneous. As the Board pointed out, Fujikawa's proposed sub-genus diverges from Wattanasin's preferred elements at least with respect to position R. Although, in hindsight, the substitution of cyclopropyl for isopropyl might seem simple and foreseeable, Wattanasin's disclosure provides no indication that position R would be a better candidate for substitution than any other. Thus, faced with Wattanasin's disclosure, it was not clear error to hold that one of ordinary skill would not be led to Fujikawa's sub-genus in particular.

Were we to extend *Ruschig*'s metaphor to this case, we would say that it is easy to bypass a tree in the forest, even one that lies close to the trail, unless the point at which one must leave the trail to find the tree is well marked. Wattanasin's preferred embodiments do blaze a trail through the forest; one that runs close by Fujikawa's proposed tree. His application, however, does not direct one to the proposed tree in particular, and does not teach the point at which one should leave the trail to find it. We therefore affirm the Board's denial of Fujikawa's motion.

VI

For the reasons we set forth above, the decision of the Board is, in all respects,

AFFIRMED.

Illinois Appellate Court
First Judicial District

First State Insurance Co. v. Alpha Delta Phi Fraternity

No. 1-94-1050

Decided November 3, 1995
(Unpublished)

TRADEMARKS AND UNFAIR TRADE PRACTICES

1. Unfair and false advertising — State and common law (§390.07)

Trial court, in construing insurance policy covering insured's liability for "advertising injury," must ascertain intent of parties to

EXHIBIT B

erty is disclosed for the prior art compound. On the basis of our understanding of the board opinion, we do not think either of these points is open for consideration because the board *accepted* appellant's arguments and applied them to the allowance of Case II claims. The board simply refused to consider the accepted factual showing with respect to the claim of Case I because, in its opinion, the invention should not be claimed as a compound. However, we note that we have previously considered the situation where an applicant shows unexpectedly and substantially improved results with respect to the *same* field of use known to the prior art and we have accepted evidence thereof as overcoming a prima facie showing of obviousness. See In re Wiechert, 54 CCPA 957, 370 F.2d 927, 152 USPQ 247, and cases therein cited.

The only point we desire to mention in connection with appellant's point (3) is that the reason the claims the board found allowable are "in another application" instead of in an application with the claim at bar, wherefore "another patent" would issue upon allowance of claim 1, is that the Patent Office required restriction. Appellant argues that the board's ruling is "tantamount to using the patent issued on McLamore's divisional application Serial No. 141,557 as a reference" which is prohibited by 35 U.S.C. 121. The solicitor strenuously opposes this argument on various grounds but we find it unnecessary to discuss it since the sole reference is the Ruschig et al. patent. Clearly, section 121 has no applicability but we think the requirement for restriction may have a bearing if it is ever argued the claims cannot be issued in separate patents. However, we do not sense that the board gave any weight to that possibility.

The decision of the board is *reversed.*

WORLEY, Chief Judge, concurs in the result.

54 CCPA 1551

Court of Customs and Patent Appeals

In re RUSCHIG, AUMULLER, KORGER, WAGNER, SCHOLZ, AND BANDER

Appl. No. 8071 Decided June 22, 1967

PATENTS

1. Prior adjudication—Applications for patent (§ 56.05)

Patent Office can reject claim as not supported by disclosure although many years ago an examiner ruled to the contrary.

2. Court of Customs and Patent Appeals—In general (§ 28.01)

Prior adjudication—Applications for patent (§ 56.05)

Under 35 U.S.C. 144, only effect of court's decision, whereby it reversed rejection of claim on prior art, was to govern further proceedings in the case; application was not returned to Patent Office for issuance.

3. Court of Customs and Patent Appeals—In general (§ 28.01)

Prior adjudication—Applications for patent (§ 56.05)

Not only may Patent Office reopen application returned by court after appeal and reject claims on newly found prior art, but it may reject claims on ground that they are not supported by disclosure of specification which has been available since application was filed.

4. Specification—Sufficiency of disclosure (§ 62.7)

Disclosure such as that found in formula and words of claim does not amount to a disclosure, sufficient to support a specific claim, of every compound a skilled chemist can see is within scope of that claim; specific claims to single compounds require reasonably specific supporting disclosure; while naming is not essential, something more than disclosure of a class of 1000, or 100, or even 48, compounds is required; given time, a chemist could name all of the half million compounds within scope of broadest claim, which claim is supported by broad disclosure; this does not constitute support for each compound individually when separately claimed.

5. Specification — Sufficiency of disclosure (§ 62.7)

In considering sufficiency of support in specification for specific compound, specification must be looked at from

standpoint of one with no foreknowledge of compound; while person motivated to make compound in preference to others would be enabled by specification to make it, this is beside the point for question is not whether he would be so enabled but whether specification discloses the compound to him, specifically, as something applicants invented.

Particular patents—Ureas

Ruschig, Aumuller, Korger, Wagner, Scholz, and Bander, New Benzene Sulfonyl Ureas and Process for Their Preparation, claim 13 of application refused.

Appeal from Board of Appeals of the Patent Office.

Application for patent of Heinrich Ruschig, Walter Aumuller, Gerhard Korger, Hans Wagner, Josef Scholz, and Alfred Bander, Serial No. 601,107, filed July 31, 1956; Patent Office Group 120. From decision rejecting claim 13, applicants appeal. Affirmed.

See also 145 USPQ 274, 147 USPQ 46.

EUGENE O. RETTER and JOHN KEKICH, both of Kalamazoo, Mich. (SIDNEY W. RUSSELL, Washington, D.C., of counsel) for appellants.

JOSEPH SCHIMMEL for Commissioner of Patents.

Before WORLEY, Chief Judge, RICH, SMITH, and ALMOND, Associate Judges, and KIRKPATRICK, Judge.*

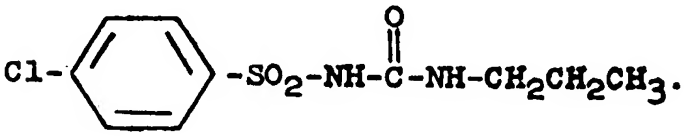
RICH, Judge.

This appeal is from the decision of the Patent Office Board of Appeals affirming the rejection of claim 13 of application serial No. 601,107, filed July 31, 1956, for "New Benzene Sulfonyl Ureas and Process for Their Preparation." Apparently The Upjohn Company has been prosecuting the application.

This case is a sequel to our decision in In re Ruschig, 52 CCPA 1238, 343 F.2d 965, 145 USPQ 274, decided April 22, 1965. There we reversed a rejection of twelve claims of this same application based on prior art. The claim on appeal is one of those claims. It reads:

> 13. N-(p-chlorobenzenesulfonyl)-N'-propylurea.

That compound is structurally identified as



It is known by the generic name chlorpropamide and is sold under the trademark Diabinese by Chas. Pfizer & Co., Inc., as an oral medication for the control of diabetes mellitus, as more fully explained in our previous opinion, wherein we also had occasion to discuss the claim 13 compound which is again before us. We refer to that opinion for a more complete exposition of the chemical nomenclature and further background.

The sole issue on this appeal is whether claim 13 is supported by the disclosure of appellants' application, a question which had not been raised in this case at the time of the prior appeal. The following events gave rise to the issue.

About a year after the present application was filed, the examiner suggested claim 13 to applicants for purposes of interference with a Pfizer application filed by McLamore, serial No. 660,064 of May 20, 1957, and September 25, 1957, the claim was added. Interference 89,091 was declared and in it McLamore moved to dissolve on the ground, inter alia, that the claim was not supported in the application at bar. The examiner held the claim was supported and denied the motion. On reconsideration, he adhered to his decision. (The suggestion of the claim and these two decisions on motions are referred to by appellants as three rulings in their favor by the Patent Office, nearly ten years ago, on the present issue.) Later the examiner dissolved the interference on his own motion on the ground claim 13 was unpatentable to the interference parties over prior art. Meanwhile both appellants and McLamore had filed divisional applications claiming methods of treating diabetes and compositions therefor, appellants' application being serial No. 185,865, filed April 9, 1962. It had two sets of claims, 1-4 for tablets and 5-8 for method of treatment. Claims 3 and 7 specified the same compound as that of claim 13. These claims were under rejection by reason of one-year statutory bars which could be overcome only

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* Senior District Judge, Eastern District of Pennsylvania, sitting by designation.

by reliance on the filing date of the present parent application which gave rise to the question whether the application contained support for the claims. In an appeal to the board in application 185,865, by an opinion of March 4, 1965, the board, having gone into the application and interference history, held that claims 3 and 7 in that application did not have support in the present application because the claim 13 compound is not disclosed therein and issued a new rejection under Rule 196 (b) on that ground.[1]

After our decision on the prior appeal, in which we reversed the rejection on prior art, the application was returned to the examiner. Since he knew of the board's action in the other application holding that the disclosure does not support the compound of claim 13, he requested and obtained from the First Assistant Commissioner authorization to reopen the case to reject claim 13 on the new ground of lack of support, which he did on June 15, 1965, as follows:

> In view of the decision of the Board of Appeals of March 4, 1965 in Serial No. 185,865, holding that claims 3 and 7 therein were not supported by the disclosure of the instant case and hence not entitled to the benefit of the date thereof, claim 13 herein which is specific to a compound, the use of which is recited in claims 3 and 7, supra, is rejected as having no specific support in this disclosure for reasons fully detailed in said decision (Appeal No. 283-74), Paper No. 25, at pages 4-7. The compound of claim 13 is not named or identified by formula and it can find support only as choices made between the several variables involved. This is not regarded as adequate support for a specific compound never named or otherwise exemplified in the specification as filed. See In re Fried 1963 C.D. 248 (page 257, first paragraph [50 CCPA 954, 312 F.2d 930, 136 USPQ 429, 435]).

Appellants then argued this rejection before the examiner who adhered to it and made it final. Reconsideration was requested and given, the examiner adhering to his view. Appellants then took the question to the board where the examiner filed an extensive Answer to their lengthy brief. The board affirmed for very much the same reasons as those stated in its opinion in deciding the same issue in application serial No. 185,865. Thus the question before us has been twice decided adversely to appellants by the Board of Appeals, the same panel hearing both appeals.[2]

In coming here, appellants raise a question in addition to the issue of support which requires preliminary consideration. They say that in this second appeal "involving the *same* and already adjudicated Claim, the United States Patent Office was without authority, or lacked jurisdiction, to reopen these proceedings (after the Court's decision) to resurrect a ground of rejection which had already been considered by the Patent Office, this lack of authority being based upon principles of, or akin to, res judicata, estoppel or laches."

In answer, the solicitor says there is no such issue before us since it was not raised before the board, is raised for the first time in this court, and was not properly raised by any reason of appeal. Appellants counter with the argument that Reason of Appeal 9, reading, "The Board of Appeals erred in matters of law," will suffice. They also say that, being a matter of "jurisdiction over subject matter," it can be raised at any time.

[1] We pass these ingenious and technical legal arguments since we prefer to say that we have considered the numerous cases relied on by appellants to support their proposition that the Patent Office cannot make this rejection because many years ago an examiner ruled to the contrary and find the point lacking in merit and unsupported by authority. We appreciate the extensive memorandum of law supplied in the appendix to appellants' brief, containing cases pro and con, and note the heavy reliance on what was said in two concurring opinions. We surmise appellants would have to agree that what precedents they have found are not, as a whole, very strong support for their theory. The words of Judge Garrett in In re Ellis, 24 CCPA 759, 86 F.2d 412, 31 USPQ 380, 382, which appellants found quoted in In re Becker, 26 CCPA 922, 101 F.2d 557, 40 USPQ 624, fairly depict the present situation, which is not much different from that prevailing in 1936,

> There is nothing unusual, certainly, about an examiner changing his view-

[1] The board opinion is reported at 147 USPQ 46. After receiving it, appellants cancelled claims 3 and 7 from application 185,865 and patent No. 3,198,706 was issued thereon, Aug. 3, 1965 to the assignee Farbwerke Hoechst Aktiengesellschaft vormals Meister Lucius & Bruning.

[2] Federico and Rosa Examiners-in-Chief, and Stone, Acting Examiner-in-Chief; opinions by Federico.

point, as to the patentability of claims as the prosecution of a case progresses, and, so long as the rules of Patent Office practice are duly complied with, an applicant has no legal ground for complaint because of such change in view.

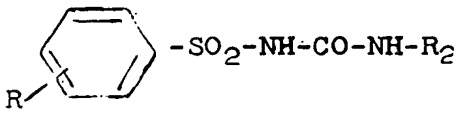
The life of a patent solicitor has always been a hard one.

[2] Appellants insinuate that in our former decision in this case we found all the claims, including claim 13, patentable. Their words are, "Presently appealed Claim 13 was also indicated as allowable by this Court." They also say that this application "was returned by this Court to the Patent Office for issuance * * *." We did neither of these things. We passed on a rejection on prior art, affirmed by the board, found it in error, and reversed the board decision. Nothing more. Under 35 U.S.C. 144 the only effect of our decision was to govern further proceedings in the case.

[3] Appellants concede that the Patent Office can reopen a case returned by this court after appeal and reject claims on newly found prior art and attempt to distinguish the present situation on the ground that the rejection now applied is not based on newly found art but on the specification which has been available since the application was filed. Further, they say the very question was adjudged in their favor long ago. We are unable to see that these differences have legal significance. See In re Citron, 51 CCPA 869, 326 F.2d 418, 140 USPQ 220. For related views on res judicata as applied to patent prosecution see our recent opinions in In re Herr, 54 CCPA ——, 377 F.2d 610, 153 USPQ 548. We hold the Patent Office had the jurisdiction and the authority to reopen prosecution and to reject claim 13 on a new ground, to the merits of which rejection we now pass.

We have quoted the examiner's rejection above. His first point was that the compound of claim 13 "was not named or identified by formula" in the specification. Appellants admit this. His next point was that it "can find support only as choices made between the several variables involved." These words are the words of Judge Smith in In re Fried, supra, a case in which we found lack of support in general disclosures. Their purport in the factual context of this case is that the reagents for the preparation of chlorpropamide are listed, with many others, in the disclosure and, as the board said, "If the proper choices of the three variables in the above formula are made, the compound in question is produced," the formula referred to being that of the family of benzene sulphonyl-ureas in which the variables are R, R_1 and R_2, to be seen in claim 1 reproduced in our former opinion. The board continued its statement, saying, "but nowhere in the specification is the particular selection indicated."

It does not seem to be contested that the general disclosure of the application encompasses something like half a million possible compounds.[3] It also discloses a number of specific compounds. Appellants' argument is that one skilled in the art would find certain "guides" in the specification which would lead him to the compound of claim 13 and that the compound is therefore disclosed. Further reliance is placed on our opinion in In re Petering, 49 CCPA 993, 301 F.2d 676, 133 USPQ 275, taken in connection with original claim 2, legally deemed a part of the disclosure, which appellants say encompasses only 48 compounds, "excluding isomers," this being in effect one of the "guides." Original claim 2 reads:

> 2. Benzenesulphonylureas of the general formula
>
> 
>
>
> wherein R is a member selected from the group consisting of chlorine and bromine and R_2 is a member selected from the group of alkyl-, alkenyl-, cycloalkyl- and cycloalkylalkyl radicals containing 2 to 7 carbon atoms.

Appellants refer to this formula as narrowing the field of selection, so to speak, and say that "excluding isomers," there are "approximately" 48 compounds within the scope of that claim all of which are "readily determinable by skilled chemists." What this amounts to is saying that skilled chemists can see that R is either Cl or Br and that

[3] In the companion case of In re McLamore (Patent Appeal 7829), concurrently decided, 154 USPQ 114, a PhD. chemist who heads the Pfizer Patent Department has made an affidavit of record in which he shows how he has calculated, on a conservative basis, including sodium and potassium salts, the number of compounds within the broad disclosure of this application to be 1,237,464. We express no view on this mathematical question. The number is very large in any event.

R_2 is any of the radicals above recited. The examiner computes that the number of possible compounds is not approximately 48 but a minimum of 1,010, "excluding stereoisomerides." He shows his calculations and we do not find a refutation of them by appellants to justify their contention the number is 48, nor any explanation of how the number 48 is arrived at. The Petering case is used for its finding that a particular reference disclosure of a subgeneric class of compounds to the number of only 20, some of which were disclosed by name, was as good as *prior art* disclosure of all 20 as though they had all been named, for the purpose of anticipating an invention, not for the purpose of disclosing it to *support* a claim. As we said in our prior opinion in this case, "Petering involved a very special situation * * * ." We do not consider the facts here to be sufficiently similar to make it pertinent. It [4] is not our view that a disclosure such as that to be found in the formula and words of claim 2, above, amounts to a disclosure, sufficient to support a specific claim, of every compound a skilled chemist can see is within the scope of that claim. Specific claims to single compounds require reasonably specific supporting disclosure and while we agree with the appellants, as the board did, that *naming* is not essential, something more than the disclosure of a class of 1000, or 100, or even 48, compounds is required. Surely, given time, a chemist could name (especially with the aid of a computer) all of the half million compounds within the scope of the broadest claim, which claim is supported by the broad disclosure. This does not constitute support for each compound individually when separately claimed.

Other "guides" allegedly *leading to* chlorpropamide argued by appellants will now be discussed. It is said eleven processes for making the many compounds of the invention are disclosed, five of which employ an "alkylamine." This is R_2 in the general formula. But in that formula there is also the variable R which may be hydrogen, chlorine, bromine, methyl, or methoxy and R_1 which may be either chlorine or bromine and, furthermore, R and R_1 may be located anywhere on the benzene ring, that is, ortho, meta, or para to the SO_2 group and adjacent or non-adjacent one another. This makes for more than a few unidentified possibilities not determined by the use of alkylamine alone. To lead to claim 13, R must be hydrogen and R_1 must be chlorine and the alkylamine, R_2, must be propylamine.

Next, it is argued in connection with these processes that in the discussion of Process (1) it is taught that the primary amine could be "*a primary butylamine or another primary alkylamine* or an alkenylamine, cyclo-alkylamine or cycloalkylalkyl-amine containing 2 to 7 or 8 carbon atoms" and that one skilled in the art could *see* that "if n-butylamine is a reactant, then ethylamine, n-propylamine, etc., are also possible reactants." We do not see that this guides one *to* the use of n-propylamine. The important words in the quotation from our point of view are "etc." and "possible". It is an old custom in the woods to mark trails by making blaze marks on the trees. It is no help in finding a trail or in finding one's way through the woods where the trails have disappeared—or have not yet been made, which is more like the case here—to be confronted simply by a large number of unmarked trees. Appellants are pointing to trees. We are looking for blaze marks which single out particular trees. We see none.

Appellants say next that the "guide" becomes more crystallized by the recitation of the alkylamines which can be employed in the four or five reactions described as using them. This list contains at least 19 primary amines which the specification says may be used. Appellants emphasize two, n-butylamine, which is elsewhere specifically disclosed as having been used, and n-propylamine. We do not see that listing the latter with the 18 others adds anything to the initial statement that one may use an alkyl amine containing from 2 to 6 carbon atoms. Propylamine is such an amine but one is not led to it in preference to the others merely by listing them all and identifying it, with the others, by name.

Finally appellants refer to two tables listing, respectively, ten and twelve specific compounds, the first being the list of specific compounds whose blood sugar lowering activity is shown in the specification, the other, which duplicates the first and adds two compounds, being the specific examples of the specification. There is no N'-n-propyl compound among them. Perhaps one of appellants' best points is that the activity table "stresses" compounds in which R_2 is a primary alkyl radical, i.e., ethyl, butyl, isobutyl and hexyl. The stress resides in the fact that eight of the ten are such compounds. And one of them, N - (4-chlorobenzenesulphonyl)-N'-n-butyl urea, is a homolog of the compound of claim 13. It must be admitted

that this is getting close. *If* n-propylamine had been used in making the compound instead of n-butylamine, the compound of claim 13 would have resulted. Appellants submit to us, as they did to the board, an imaginary specific example patterned on specific example 6 by which the above butyl compound is made so that we can see what a simple change would have resulted in a specific supporting disclosure being present in the present specification. The trouble is that there is no such disclosure, easy though it is to imagine it. It is equally easy to imagine that the compound of claim 13 might have been named in the specification. Working backward from a knowledge of chlorpropamide, that is by hindsight, it is all very clear what route one would travel through the forest of the specification to arrive at [5] it. But looking at the problem, as we must, from the standpoint of one with no foreknowledge of the specific compound, it is our considered opinion that the board was correct in saying:

> Not having been specifically named or mentioned in any manner, one is left to selection from the myriads of possibilities encompassed by the broad disclosure, with no guide indicating or directing that this particular selection should be made rather than any of the many others which could also be made.

Appellants refer to 35 U.S.C. 112 as the presumed basis for this rejection and emphasize language therein about *enabling* one skilled in the art to *make* the invention, arguing therefrom that one skilled in the art would be enabled by the specification to make chlorpropamide. We find the argument unpersuasive for two reasons. First, it presumes some motiviation for wanting to make the compound in preference to others. While we have no doubt a person so motivated would be enabled by the specification to make it, this is beside the point for the question is not whether he would be so enabled but whether the specification discloses the compound to him, specifically, as something appellants actually invented. We think it does not. Second, we doubt that the rejection is truly based on section 112, at least on the parts relied on by appellants. If based on section 112, it is on the requirement thereof that "The specification shall contain a written description *of the invention* * * *." (Emphasis ours.) We have a specification which describes appellants' invention. The issue here is in no wise a question of its compliance with section 112, it is a question of *fact: Is the compound of claim 13 described therein?* Does the specification convey clearly to those skilled in the art, to whom it is addressed, in any way, the information that appellants invented that specific compound? Having considered the specification in the light that has been shed on it by all the arguments pro and con, we conclude that it does not.

The decision of the board is *affirmed.*

Patent Office Trademark Trial and Appeal Board

In re SIGNAL OIL AND GAS COMPANY

Decided June 13, 1967

TRADEMARKS

1. **Identity and similarity—Words and symbols (§ 67.413)**

"Hancock 500" does not so resemble "500" above "Platolene" that confusion is likely.

Appeal from Examiner of Trademarks.

Application for registration of trademark of Signal Oil and Gas Company, Serial No. 186,777. From decision refusing registration, applicant appeals. Reversed.

FRASER & BOGUCKI, Los Angeles, Calif., and WYNNE & FINKEN, Washington, D.C., for applicant.

Before LEACH, WALDSTREICHER, and SHRYOCK, Members.

SHRYOCK, Member.

An application has been filed to register "HANCOCK 500" for gasoline, use since August 10, 1959, being asserted. Applicant is the owner of various registrations which include the name "HANCOCK" for petroleum products.[1]

Registration has been refused on the ground that applicant's marks so resembles the registered mark, reproduced below, for gasoline[2] that there would be a likelihood of confusion or mistake.

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[1] Reg. No. 213,522, issued June 1, 1926, second renewal; Reg. No. 276,862, issued Oct. 28, 1930, renewed; and Reg. No. 303,972, issued June 13, 1933, renewed.

[2] Reg. No. 724,701, issued Dec. 5, 1961.